

K960245

I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

1. Name and Address

This Summary of Safety and Effectiveness is being submitted by Pro-Dentec, Inc., P.O. Box 4129, Batesville, Arkansas 72503. The telephone number is 501-793-2300.

2. Name of the Device

The device is generally known as an Electronic Periodontal Probe.

3. Identification of Predicate Device(s)

Florida Probe Corporation's "Florida Probe," K875076, and the manual Michigan periodontol probes.

4. Description of the Device

The device is a periodontal probe which is used by dental professionals during periodontal examinations. The device consists of a control unit, a transducer connected by a cable to the control unit and single use, disposable handpieces.

5. Intended Use of the Device

Pro-Dentec's VICTOR Interactive Probe is an automated periodontal probe intended for use during periodontal examinations to measure and chart the depth of a gingival sulcus in millimeters.

6. Comparison of Technological Characteristics

The differences between Pro-Dentec's VICTOR Interactive Probe and the predicate device are minor and do not impact the safety and effectiveness of the device in any significant way.